REMARKS/ARGUMENTS

Claims 1-21, 25-31, 35, 37, 38 and 40-47 are pending. Claims 1-16 have been withdrawn from consideration. Claims 22-24, 32-34, 36 and 39 were previously cancelled. In the Office Action, the Examiner rejected claims 17-21, 25-31, 35, 37, 38 and 40-47 on various grounds. The Applicants respond to each ground of rejection as subsequently recited herein and requests reconsideration of the present application.

35 U.S.C. §103 Rejections

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art references when combined must teach or suggest all the claim limitations. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Finally, there must be a reasonable expectation of success. *See* MPEP 2143.

A. Claims 17-21, 24, 25, 28-31, 34-38, 40, 41, 43-45 and 47 have been rejected under 35 U.S.C.§ 103(a) as being unpatentable over Fearnot (US Patent 5,380,299) in view of Mao et al., (US Patent Publication 2003/0022216).

As a preliminary matter, the Examiner's initial rejection states that claims 17-25 and 28-38 are rejected over Fearnot in view of Mao. However, claims 22-24, 34, 36 and 38 were cancelled in the amendment to the claims filed June 12, 2006. Also, in addition to claims 17-25 and 28-38, the Examiner addressed claims 40, 41, 43-45 and 47 in this same rejection. In light of this, the Applicants respond to the rejection of pending claims 17-21, 25, 28-31, 35, 37, 40, 41, 43-45 and 47. The Applicants traverse this rejection.

The Applicants respectfully assert that the Fearnot patent in view of the Mao publication, fails to disclose, teach, or suggest all of the claim limitations of independent claims 17, 25 and 35. Specifically, Fearnot in view of Mao does not disclose teach or suggest:

1) a drug-polymer coated stent that includes a stent framework, a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and *a cured first polymer*, and at least one thin *barrier layer positioned*

between one or more thin drug-polymer layers, wherein the at least one thin barrier layer includes *a cured second polymer*, as recited in independent claim 17;

2) a system for treating a vascular condition, that includes a catheter and a coated stent coupled to the catheter, the coated stent including a stent framework and a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers and at least one thin *barrier layer positioned between* one or more thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and *a cured first polymer* and wherein the thin barrier layer includes *a cured second polymer*, as recited in independent claim 25; and

3) a method of treating a vascular condition that includes the step of inserting a drug-polymer coated stent within a vessel of a body, the drug-polymer coated stent including a laminated drug-polymer coating having a plurality of thin drug-polymer layers and at least one thin *barrier layer positioned between* one or more thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and *a cured first polymer* and wherein the thin barrier layer includes *a cured second polymer*, wherein the first polymer is cured with one of thermal activation, electrical activation, or ionizing irradiation as recited in independent claim 35.

The Examiner continues to rely on the Fearnot patent to teach or otherwise suggest "at least one thin barrier layer positioned between one or more thin drug-polymer layers" as recited in claims 17, 25 and 35. The Examiner cites to column 2 lines 10-25 and figure 5 of the Fearnot patent to teach these limitations. However, column 2, lines 10-25, merely teaches a method of coating a medical device surface by dipping the device into a solution containing a thrombolytic agent, allowing the solution to dry and repeating the dipping and drying, if necessary, to obtain the desired concentration or quantity of the thrombolytic agent on the device surface. Figure 5 of the Fearnot patent merely teaches a stent framework having a multi-layer coating, the multi-layer coating having three layers of an antithrombogenic agent and three layers of a thrombolytic agent applied over the antithrombogenic layers (see Fearnot col. 3 lines 47-50). Nowhere within the cited portions or the entirety of the Fearnot patent, does the Fearnot patent teach or fairly suggest that any of the layers of the multi-layer coating is a barrier layer as claimed and described by the Applicants. The mere fact that the Fearnot patent teaches a multi-layer coating does not necessarily teach that any of the layers are barrier layers. Therefore, the Fearnot patent

does not teach at least one thin barrier layer positioned between one or more thin drug-polymer layers" as recited in claims 17, 25 and 35. The Mao publication does not cure this defect. For at least this reason, claims 17, 25 and 35, and the claims depending therefrom, are patentable over the Fearnot patent in view of the Mao publication.

Additionally, the Fearnot patent in view of the Mao publication does not teach or suggest that the thin drug-polymer layers include a "cured first polymer" and that the at least one "barrier layer includes a cured second polymer" as claimed and described by the Applicants (see Applicants' Specification para. [00030] at page 8 lines 23-28). The Fearnot patent does not teach or suggest that the polymer within the coating solution is cured, merely that the coating solution is dried. The Examiner relies on the Mao publication to teach a cured first polymer and a cured second polymer as claimed in independent claims 17, 25 and 35. The Examiner alleges that "it would have been obvious to one having skill in the art at the time the invention was made to cure the coatings of Fearnot with the methods provided by Mao in order to cure and bond the coatings to each other and the support member" see page 3 of the present office action). The allegation is misplaced because there is no motivation to combine these references as required to sustain an obvious type rejection.

The Fearnot patent teaches that the antithrombogenic agent and the thrombolytic agent can be applied to the surface in separate layers or mixed in a single solution for coating onto the device surface (see col. 3 lines 51-57). Furthermore, the Fearnot patent does not teach or suggest a desire to minimize drug-drug interactions or a desire to retain the therapeutic agents within their associated layers until the coated stent is deployed in the body as is provided by the Applicants (see para. [00035]). Therefore, Fearnot does not teach or suggest the need for curing the therapeutic agent solution. Consequently, one of ordinary skill in the art would not be motivated to combine the teachings of the Fearnot patent with the teachings of the Mao publication in such a manner as to arrive at the invention as claimed by the Applicants. As there is no motivation to combine these references, the combination of the Fearnot patent with the Mao publication is improper. For at least this additional reason, the rejection of independent claims 17, 25 and 35 as being unpatentable over the Fearnot patent in view of the Mao publication cannot be sustained.

For these reasons, the Applicants respectfully request the withdrawal of the rejection of independent claims 17, 25 and 35 as being unpatentable over the Fearnot patent in view of the Mao publication.

Claims 18-21, 28-31, 37, 40, 41, 43-45 and 47 each depend from one of independent claims 17, 25 and 35 and include all of the elements of their respective independent claim. For at least this reason, dependent claims 18-21, 28-31, 37, 40, 41, 43-45 and 47 are patentable over the Fearnot patent in view of the Mao publication. As such, the Applicants respectfully request the withdrawal of the rejection of claims 18-21, 28-31, 37, 40, 41, 43-45 and 47 as being unpatentable over the Fearnot patent in view of the Mao publication.

B. Claims 26 and 27 have been rejected under 35 U.S.C.§ 103(a) as being unpatentable over Fearnot in view of Mao and in further view of Guruwaiya (US Patent 6,251,136).

Claims 26 and 27 depend from independent claim 25 and include all of the elements and limitations of independent claim 25 and, thus, are allowable for at least the same reasons as those stated above for claim 25. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claims 26 and 27 under § 103(a) as being unpatentable over Fearnot in view of Mao and in further view of Guruwaiya.

C. Claims 42 and 46 have been rejected under 35 U.S.C.§ 103(a) as being unpatentable over Fearnot in view of Mao and in further view of Helmus et al., (US Patent 5,447,724).

Claims 42 and 46 depend from independent claims 17 and 25, respectively, and include all of the elements and limitations of independent claims 17 or 25 and, thus, are allowable for at least the same reasons as those stated above for claims 17 and 25. Furthermore, where an independent claim is non-obvious, any claim depending therefrom is also non-obvious. *See*, MPEP 2143. Applicants, therefore, request the withdrawal of the rejection of dependent claims 42 and 46 under § 103(a) as being unpatentable over Fearnot in view of Mao and in further view of Helmus.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

/Catherine C. Maresh, Reg. No. 35,268/
Catherine C. Maresh
Registration No. 35,268
Attorney for Applicant

Medtronic Vascular, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
Facsimile No.: (707) 543-5420